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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,047	04/15/2004	Steven Odrich	2755.025US1	7403

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
12/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No.	Applicant(s)	
	10/825,047	ODRICH, STEVEN	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11, 13 - 19, 21 - 44* is/are pending in the application.

4a) Of the above claim(s) *13, 14, 16, 18, 19, 23 - 28, 32, 35, 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 14, 15, 17, 21, 22, 29 - 31, 33, 34, 37 - 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 22, 2009 has been entered.

Petition to Change Inventorship under 37 CFR 1.48(b)

2. In view of the papers filed February 11, 2008, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Liane C. Glazer.

The issuance of a corrected filing receipt and correction of Office records to reflect the inventorship as corrected has been requested. The corrected filing receipt will be mailed separately from this Office Action.

Oath/Declaration

3. The oath or declaration filed February 11, 2008 is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Claim Objections

4. Claims 39 and 43 are objected to because of the following informalities: it appears that the active ingredients listed in the claim are misspelled. The Applicants recite "travaprost" and "bimataprost" and the Examiner in unaware of these being alternate spelling for these prostaglandins that are known in the art as "travoprost" and "bimatoprost". Appropriate correction is required.

Claim Rejections - 35 USC § 112 – 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is both a new matter and a written description rejection. The Examiner was unable to find support in the application as originally filed for the limitation "wherein the exterior surface portion of the implant body ... is configured to provide the sustained release to tissue at or near the eye for a time period between 3-6 months after implant". If Applicant is in disagreement with the Examiner regarding support for the amended claim, Applicant is respectfully requested to point to page and line number wherein support may be found for the instant invention.

This phrase is also rejected under the written description provision. No description as to what configurations (e.g., pore structure, an additional membrane) that allow for the sustained release are given.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is insufficient antecedent basis for the limitation of

"implant body" in line 1 of the claim. The term "substantially saturated" is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Something is either saturated or not saturated so how "substantially saturated" differs from "saturated" is not clear. This phrase could also be referring to the fraction of the implant body that is saturated with the active agent, but again it is unclear what fraction of the implant body would need to saturated in order for this claim limitation to be met. Please clarify.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 11, 15, 17, 21, 22, 30, 31, 34, 37 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ness (US 3,828,777).

Figure 4 discloses an ocular insert according to Ness (col 8, ln 19 - 33). The device is comprised of a body of microporous drug release rate controlling matrix material (**40**) having drug (**41**) dispersed throughout. Part **41** functions as both the reservoir and the release rate controlling mechanism to continuously dispense a

metered amount of drug to the eye and tissue over a prolonged period of time (col 8, ln 23 - 28). As can be seen in figure 2, the implant body extends from a proximal end portion configured to seat at or near a lacrimal punctum when implanted to a distal portion configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted. The drug is a medicine and the antibiotics or sulfonamides disclosed (col 8, ln 56 – 67) read on medications for treatment of an eye.

The exterior surface is configured to allow for the sustained release active ingredient over a prolonged period of time (col 8, ln 35 – 37). The ocular implant of Ness has the same structure as that recited in the instant specification and claims and therefore the exterior surface is configured in the manner required by claim 22.

The materials that make up the implant (the drug release rate controlling materials) are biological compatible with the physical environment of the eye and insoluble (col 4, ln 56 – 65) and at least some of the various materials listed, such as polydimethylsiloxane (col 11, ln 65) are inert.

11. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (US 3,949,750). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 22, 2008 and June 9, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the prior art must disclose each element of the claimed invention arranged as in the claims. When a reference relied upon is subject to more than one interpretation, the interpretation of one of

ordinary skill in the art must be followed, who is, in part, defined by considering the types of problems encountered in the prior art and the educational level of workers in the filed. Freeman discloses dispensing drug from a reservoir within a plug, but not that the entire porous or absorbent implant body stores or dispenses medication as claimed by Applicant. The reservoir of Freeman does not and cannot extend beyond that used for drug delivery to an eye. One of ordinary skill in the art would understand that section of the reference (col 5, lines 8 – 14) not as asserted by the Office Action. Freeman expressly teaches against disposing an active agent at or near the distal tip or deeper-inserted end portion of a punctual plug. The educational level of workers in the ophthalmology filed dictates that Freeman teaches against disposing an active agent at or near the distal portion of a punctual plug, in contrast to Applicant's claimed device. Col 2, ln 40 – 42 indicates delivery to the eye while preventing such medication from entering the nose and subsequent systemic body absorption. Therefore, Freeman does not recite an ocular implant comprising a porous or absorbent implant body and an active agent disposed entirely throughout the implant body as recited in claim 11. Claim 30 requires a porous or absorbent implant body incorporating an active agent from a proximal end portion to a distal end portion. Freeman does not disclose an ocular implant comprising a porous or absorbent implant body incorporating an active agent from the proximal to distal ends.

These arguments are unpersuasive. The cited case of *Custom Accessories Inc.*, teaching away and the interpretation and skill of one of ordinary skill in the art are germane to obviousness rejections made under 35 U.S.C. 103 and not, as in the instant

case, anticipation rejections made under 35 U.S.C. 102. Anticipation is a factual inquiry as to whether the prior art's disclosure is identical to that of the claim. If, by a preponderance of the evidence, the Office shows the prior art to be identical then an anticipation rejection is proper. There is no room for inquiry as to what the artisan would believe. Because the artisan's beliefs are not germane to an anticipation rejection, this argument cannot be persuasive.

The Office must give the claims the broadest reasonable interpretation during examination. Any embodiment of the prior art falling within the scope of the claims anticipates those claims. The claims do not require that the entire implant be comprised of a porous of absorbent material. Rather, in claim 1 the implant comprises "a porous or absorbent implant body...and an active agent disposed entirely throughout the porous or absorbent implant body". One embodiment of the claim requires that 100% of the active agent be within the porous or absorbent implant body, but does not require that the ocular implant be 100% porous or absorbent material. The tissue to which the active agent is delivered is expressed in the alternative as "tissue at or near one or both of an eye or a nasolacrimal system". Therefore, even if the plug only delivered the active agent to the eye because of the location of the reservoir, this limitation would be met.

The teachings of the references are not limited only to the examples. At column 5, ln 8 - 10 Freeman discloses that "the plugs **20, 20'**... may be of medication-impregnable porous material" or only the head portion of the plug may be made of such a material. When part 20 or 20' is made of the porous material, the entire ocular implant is comprised of a porous or absorbent material having the requisite configuration. When

the plug is impregnated with ophthalmic medication (col 2, ln 27 – 33), all of the active agent will be disposed entirely throughout the porous or absorbent implant body and will end from the proximal end to the distal end. Freeman discloses all elements of the claims and thus anticipates the instant claims.

12. Claims 11, 15, 16, 21, 22, 29 – 31, 33 - 39, 40 – 42 and 44 were rejected under 35 U.S.C. 102(b) as being anticipated by Cohan et al. (US 6,196,993). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 22, 2008 and June 9, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Cohan recites that that the insert body is composed of a material that is impermeable to the medication that fills the reservoir. The operability relies on the body being impermeable so that the medication within the reservoir is directed out a port to control the rate of flow. This arrangement is in contrast to claim 11 which recites an active agent disposed entirely throughout the porous or absorbent implant body. To assert that the entire body could include active agent runs afoul of Cohan's reliance on the proximally-located pore that is required for controlled release of the medication. Applicant submits that the new claim language clearly conveys that the entire implant body including active agent is made of a porous or absorbent material. Claim 30 requires the active agent to be incorporated from a proximal end portion to a distal end portion on contrast to the internal reservoir with materials that are impermeable, unsaturateable material.

These arguments are unpersuasive. The device of Cohan et al. shown in figure 6 includes a wick extension that transmits the medication from the internal reservoir and is preferably made from an absorbent, cloth like material (col 5, ln 21 – 33). This wick extension is a porous or absorbent implant body that extends from a proximal end portion to a distal end portion. The rope like shape of the wick extension is configured to seat at or a lacrimal punctum and is also configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted. These claims are drawn to products so the implantation and site of implantations are intended use language. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The rope like structure is configured as required by the instant claims. Once the reservoir is filled with active agent, the active agent will wick into the wick extension, and the entirety of the absorbent material present in the ocular implant will contain active agent, meeting the limitation of "an active agent disposed entirely throughout the porous or absorbent implant body". This embodiment also contains active agent dispersed from a proximal to distal end.

The claims use the transitional phrase of "comprising" so the claim does not exclude other elements being present in the ocular implant, such as walls for the reservoir that are impermeable to the medication. This device will, when implanted, deliver active agent on a sustained release basis to tissue at or near an eye.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 11, 15, 17, 21, 22, 30, 31, 34, 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ness (US 3,828,777).

Figure 4 discloses an ocular insert according to Ness (col 8, ln 19 - 33). The device is comprised of a body of microporous drug release rate controlling matrix material (**40**) having drug (**41**) dispersed throughout. Part **41** functions as both the reservoir and the release rate controlling mechanism to continuously dispense a metered amount of drug to the eye and tissue over a prolonged period of time (col 8, ln 23 - 28). As can be seen in figure 2, the implant body is configured to seat at or near a lacrimal punctum when implanted to a distal portion configured for insertion through the lactimal punctum into a lacrimal canaliculus when implanted. The drug is a medicine and the antibiotics or sulfonamides (col 8, ln 56 – 67) read on medication for treatment of an eye.

Ness does not explicitly describe a prolonged release time period of active ingredient of 3-6 months.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare an ocular device with a 3 – 6 month period of drug release. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Ness discloses that the insert provides prolonged release over a prolonged period of time and that devices containing different amounts of drug for use for different time periods and releasing drug at higher or lower ate are also readily made by the invention (col 8,lnm

34 – 55). The length of time for drug release from the insert is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal length of time for drug release based on the particular active agent selected, the dose of the active ingredient to be delivered and how frequently the patient will require treatment and/or time between insertion of a new ocular insert.

The exterior surface is configured to allow for the sustained release active ingredient over a prolonged period of time (col 8, ln 35 – 37). The ocular implant of Ness has the same structure as that recited in the instant specification and claims and therefore the exterior surface is configured in the manner required by claim 22.

The materials that make up the implant (the drug release rate controlling materials) are biological compatible with the physical environment of the eye and insoluble (col 4, ln 56 – 65) and at least some of the various materials listed, such as polydimethylsiloxane (col 11, ln 65) are inert.

17. Claims 11, 14, 15, 17, 21, 22, 29 – 31, 33, 34, 37, 38, 40 – 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ness as applied to claims 11, 15, 17, 21, 22, 30, 31, 34, 37 and 41 above, and further in view of Cohan et al. (US 6,196,993).

As described in greater detail above, Ness discloses an ocular implant made entirely from a porous or absorbent material and active agent that provides for the prolonged release of active agent to the eye.

Ness does not disclose the inclusion of latanoprost as a drug or an outer stopper structure or an inner stopper structure.

Cohan et al. discloses ophthalmic inserts for the sustained release of medication to the eye comprising a body portion sized to pass through a lacrimal punctum with a collarete structure that sits on the exterior or the lacrimal punctum (abstract). That collarete forms an outer stopper structure configured to seat against the lacrimal punctum. Part 38 can be included and shown in figure 3 to help secure the insert within the canaliculus (col 4, ln 45 – 48). Anti-glaucoma drugs such as latanoprost can be administered using an ocular implant that releases drug over a sustained period of time (col 7, ln 5 – 8).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate medication for the treatment of glaucoma such as latanoprost in the ocular insert of Ness. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Cohan et al. discloses that latanoprost is a drug suitable for sustained administration to the eye by implantation of a drug releasing implant.

It also would obvious to include an outer stopper structure to prevent the device from being inserted too deeply and/or an inner stopper structure to aid in holding the device in place inside the canaliculus as taught by Cohan et al.

18. Claims 11, 14, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 - 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ness and Cohan et al. as applied to claims 11, 14, 15, 17, 21, 22, 29 – 31, 33, 34, 37, 38, 40 – 42 and 44 above, and further in view of Robertson (US 2002/0193441).

As discussed in greater detail above, Ness and Cohan disclose an ocular implant to dispense a glaucoma medication such as latanoprost over a prolonged period of time. The inclusion of inner and/or outer stoppers aids in proper localization of the device and retention of the device in that position.

Neither reference discloses travoprost or bimatoprost as medication for the treatment of glaucoma.

Robertson discloses that latanoprost, travoprost and bimatoprost are prostaglandin analogs that reduces intraocular pressure and treats glaucoma (¶ [0011]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate travoprost or bimatoprost as the anti-glaucoma active agent in the ocular implant taught by Ness and Cohan et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Robertson teaches that the glaucoma medication latanoprost taught by Cohan et al. is functionally equivalent to travoprost and bimatoprost, which are also prostaglandin analogs useful in the treatment of glaucoma.

19. Claims 11, 15, 16, 21, 22, 29 – 31, 33 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 3,949,750) in view of Bhushan (US 2004/0137068). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 22, 2008 and June 9, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Freeman teaches against incorporating an active agent at or near the distal or deeper inserted end portion of his punctual plug.

These arguments are unpersuasive. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). (MPEP 2123). Furthermore, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). **MPEP 2123**, emphasis added. Freeman discloses that the entire plug, or only the head region, may be made from absorbent material and therefore does not teach away from the construction of an implant in more than the head region of the ocular implant is made from porous or absorbent material. Bhushan was cited for its teaching of the time frame over which drug delivery takes place and as discussed in greater detail above, Bhushan does not need remedy any alleged deficiencies of Freeman regarding the claim limitations regarding the structure of the ocular implant recited in claims 11 or 30.

20. Claims 11, 15, 17, 22, 22, 29 – 31, 33, 34, 37, 38, 40 - 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 3,949,750) in view of Cohan et al. (US 6,196,993). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 22, 2008 and June 9, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds discussed above in regards Freeman and Cohan when applied individually. The combination also fails to teach or suggest all of the elements of claims 11 and 30

These arguments are unpersuasive. That each reference individually teaches all the elements of claims 11 and 30 is discussed in greater detail above. Therefore, all of the claimed elements are recited so this rejection is maintained for the reasons of record.

21. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman and Cohan et al. as applied to claims 11, 15, 17, 22, 22, 29 – 31, 33, 34, 37, 38, 40 - 42 and 44 above, and further in view of Robertson (US 2002/0193441).

Freeman discloses a punctual plug in which the head or body has a medication-discharge from an exterior surface portion of the plug body (col 5, ln 8 – 14) and provides a sustained release of the active ingredient from the plug. The portion of the implant body comprised of porous or absorbent material has the active agent disposed entirely throughout that portion. A variety of active agents, including anti-glaucoma

agents such as latanoprost as taught by Cohen et al. (col 7, ln 4 – 10) can be administered using such ocular implants. (See the June 9, 2009 Office Action, section 13 for a full discussion of the teachings of these references.)

Neither reference discloses travoprost or bimatoprost as medication for the treatment of glaucoma.

Robertson discloses that latanoprost, travoprost and bimatoprost are prostaglandin analogs that reduces intraocular pressure and treats glaucoma (¶ [0011]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate travoprost or bimatoprost as the active agent in the ocular implant taught by Freeman, devices which can be used to deliver medications for the treatment of glaucoma as taught by Cohan et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Robertson teaches that the glaucoma medication latanoprost taught by Cohan et al. is functionally equivalent to travoprost and bimatoprost, which are also prostaglandin analogs useful in the treatment of glaucoma.

22. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 37, 38, 40 – 42 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cohan et al. (US 6,196,993) in view of Bhushan (US 2004/0137096). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 22, 2008 and June 9, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds that neither reference discloses "a porous or absorbent implant body" extending from a proximal end portion to a distal end portion and an active agent disposed entirely throughout the porous or absorbent body implant. Applicant further points out that the amount of medication that can be contained in Applicant's claimed ocular implant is only limited by the size of the implant body and not the size of an internal reservoir within the body

These arguments are unpersuasive. A more specific discussion of how Cohan et al. meets the limitations of the claims is found above. It is unclear what relevance the amount of medication to the instant rejections. A particular amount of medication is not recited in the instant claims. If Applicants are asserting that the reservoir of Cohan could not administer the active agent for a time period of between 3-6 months, then the Examiner requires more evidence to support this argument. Arguments without factual support are mere allegations and are not found persuasive.

23. Claims 11, 15, 17, 21, 22, 29 – 31, 33 and 37 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohan et al. (US 6,196,993) in view of Robertson (US 2002/0193441).

Cohan et al. discloses ophthalmic inserts for the sustained release of medication to the eye comprising a body portion sized to pass through a lacrimal punctum with a collarete structure that sits on the exterior or the lacrimal punctum (abstract). How the structures of Cohan et al. meet the limitations of the instant claims can be found above.

Cohan et al. does not disclose travoprost or bimatoprost as medication for the treatment of glaucoma.

Robertson discloses that latanoprost, travoprost and bimatoprost are prostaglandin analogs that reduces intraocular pressure and treats glaucoma (¶ [0011]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate travoprost or bimatoprost as the active agent in the ocular implant taught by Cohan et al., devices which can be used to deliver medications for the treatment of glaucoma as taught by Cohan et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Robertson teaches that the glaucoma medication latanoprost taught by Cohan et al. is functionally equivalent to travoprost and bimatoprost, which are also prostaglandin analogs useful in the treatment of glaucoma.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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NMW